UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 27, 2022**

Eagle Pharmaceuticals, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**001-36306**	**20-8179278**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

50 Tice Boulevard, Suite 315 **Woodcliff Lake, NJ**	**07677**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(201) 326-5300**

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligations of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol**	**Name of each exchange on which registered**
Common Stock (par value $0.001 per share)	EGRX	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 27, 2022, Eagle Pharmaceuticals, Inc., or the Company, and Enalare Therapeutics Inc., or Enalare, issued a press release announcing that Enalare secured a contract for up to $50.3 million from the Biomedical Advanced Research and Development Authority to advance an intramuscular formulation of ENA-001. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information furnished under this Item 7.01, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or subject to the liabilities of that section. The information shall not be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

Exhibit No.	Description
99.1	Press Release of the Company, dated September 27, 2022.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: September 27, 2022

EAGLE PHARMACEUTICALS, INC.

By: /s/ Scott Tarriff
Scott Tarriff
Chief Executive Officer

Exhibit 99.1

For Immediate Release

Eagle Pharmaceuticals and Enalare Therapeutics Announce Additional Award Worth Up to $50 Million from BARDA to Advance an Intramuscular ("IM") Formulation of ENA-001

-- ENA-001, a new chemical entity with a unique mechanism of action, is being developed as an agnostic respiratory stimulant for use in multiple patient populations experiencing acute respiratory depression --

-- Development is under way of intramuscular formulation for treatment of community drug overdose and as a medical countermeasure for mass casualty events --

-- Expanded funding supports development of an IM formulation of ENA-001 from pre-clinical toxicology through filing for FDA approval for use in the United States --

WOODCLIFF LAKE, N.J. and PRINCETON, N.J. — September 27, 2022 — Eagle Pharmaceuticals, Inc. (Nasdaq: EGRX) ("Eagle" or the "Company") and Enalare Therapeutics Inc. ("Enalare") today announced that Enalare has secured a contract for up to $50.3 million from the Biomedical Advanced Research and Development Authority ("BARDA"), part of the Administration for Strategic Preparedness and Response in the U.S. Department of Health and Human Services (contract number 75A50122C00072). In partnership with BARDA, ENA-001 is being developed in an intramuscular ("IM") formulation for potential use in patients experiencing community drug overdose and as a potential medical countermeasure for mass casualty events.

The contract is awarded in stages based on the achievement of established milestones and deliverables and provides funding for Enalare to perform pre-clinical toxicology studies, human clinical studies, drug and device manufacturing, and submission of the regulatory file to the U.S. Food and Drug Administration ("FDA") for a formulation of ENA-001 suitable for community use. The first phase of the contract, which provides approximately $6.0 million to complete activities through the initial Phase 1 study, coincides with grant support from the National Institute on Drug Abuse ("NIDA"), part of the National Institutes of Health.

"Respiratory depression can be life threatening. This award provides critical non-dilutive funding to Enalare to accelerate the development of an IM formulation for ENA-001, which could potentially enable more rapid deployment in emergency situations. The pre-clinical work is going very well, and the BARDA contract provides support along the development and regulatory pathway toward FDA approval of ENA-001 for use in the United States. We believe this is a promising opportunity to address a serious, unmet issue in our society, and adds further to our enthusiasm for our agreement with Enalare," stated Scott Tarriff, President and Chief Executive Officer of Eagle Pharmaceuticals.

"We are pleased to expand our partnership with BARDA on the development of ENA-001 – a novel compound with a unique mechanism of action as an agnostic respiratory stimulant," said Herm Cukier, President and CEO of Enalare Therapeutics. "ENA-001's rapid and proven ventilatory stimulation, irrespective of the cause of the respiratory depression, is critical for effective post-exposure therapy given the urgency for treatment and the unknowns associated with many chemical threats. Drug overdoses continue to ravage our communities, and with this new contract, we can accelerate our efforts to achieve our mutual goal of developing an innovative and rapid treatment for respiratory depression in a variety of settings," concluded Cukier.

The new award builds on an existing partnership between Enalare and the BARDA DRIVe ReDIRECT (Repurposing Drugs in Response to Chemical Threats) program. During that project, Enalare performed work to develop a formulation of ENA-001 that is suitable for intramuscular administration, which is much preferred for emergency use in the community.

The funding is provided via Biomedical Advanced Research and Development Authority to support the advanced research and development of medical countermeasures (MCM) for chemical, biological, radiological and nuclear (CBRN) agents, pandemic influenza, and emerging infectious diseases that threaten the U.S. civilian population.

In August 2022, Eagle made an equity investment of $12.5 million in Enalare, with a commitment to invest another $12.5 million six months later and two potential follow-on equity investments of $15 million each contingent upon (i) the commencement of the ENA-001 Phase 2 clinical trial, and (ii) the ENA-001 Phase 2 clinical trial reaching 50% enrollment. Eagle also has the option to acquire the remaining Enalare shares for an aggregate purchase price ranging from $100-$175 million plus royalty rights ranging from 9%-12% on all future global net sales of any Enalare product, paid to the ex-Eagle holders of Enalare shares at the time of acquisition.

The development of ENA-001 is also supported by the National Institute on Drug Abuse ("NIDA") of the National Institutes of Health ("NIH") under award number R44DA057133. The content of this document is the responsibility of its authors and does not necessarily represent the official views of the National Institutes of Health.

About ENA-001

Enalare's lead compound, ENA-001, is a one-of-a-kind new chemical entity (NCE) designed as an agnostic respiratory stimulant. The compound has a novel mechanism of action that affects ventilation via the peripheral chemoreceptor pathways in the carotid body. It utilizes the body's own ventilation control system to beneficially influence breathing and has been shown to be effective and well tolerated in five human studies to date. With its novel mechanism of action and based on findings to date, it could potentially improve the lives of those impacted by several life-threatening conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity. ENA-001 is an investigational compound and is not approved for use by the FDA.

About Enalare Therapeutics Inc.

Enalare Therapeutics Inc. is a clinical-stage biopharmaceutical company dedicated to developing novel therapies for patients suffering from life-threatening acute respiratory and critical care conditions, including community drug overdose, post-operative respiratory depression, and apnea of prematurity. Enalare maintains global rights to its novel compounds and intends to start additional clinical trials with ENA-001 for several indications in the near term.

About Eagle Pharmaceuticals, Inc.

Eagle is a fully integrated pharmaceutical company with research and development, clinical, manufacturing and commercial expertise. Eagle is committed to developing innovative medicines that result in meaningful improvements in patients' lives. Eagle's commercialized products include vasopressin, PEMFEXY®, RYANODEX®, BENDEKA®, BELRAPZO®, TREAKISYM® (Japan), and BYFAVO® and BARHEMSYS® through its wholly owned subsidiary Acacia Pharma Inc. Eagle's oncology and CNS/metabolic critical care pipeline includes product candidates with the potential to address underserved therapeutic areas across multiple disease states. Additional information is available on Eagle's website at www.eagleus.com.

Forward-Looking Statements

This press release contains "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, and other securities law. Forward-looking statements are statements that are not historical facts. Words and phrases such as "anticipated," "forward," "will," "would," "may," "remain," "potential," "prepare," "expected," "believe," "plan," "near future," "belief," "guidance," and similar expressions are intended to identify forward-looking statements. These statements include, but are not limited to, statements with respect to the development of, potential benefits of and potential FDA submission for ENA-001, including a potential IM formulation that could potentially enable more rapid deployment in emergency situations and the potential to develop an innovative and rapid treatment for respiratory depression in a variety of settings; expectations with respect to the BARDA award providing funding to Enalare to accelerate the development of ENA-001, including the potential receipt of contingent funding from BARDA by Enalare; the achievement of milestones and deliverables; the potential further investment by Eagle in Enalare; and Eagle's development programs, products and pipeline. All of such statements are subject to certain risks and uncertainties, many of which are difficult to predict and generally beyond the Company's or Enalare's control, that could cause actual results to differ materially from those expressed in, or implied or projected by, the forward-looking information and statements. Such risks and uncertainties include, but are not limited to: the impacts of the ongoing COVID-19 pandemic, including interruptions or other adverse effects on clinical trials and delays in regulatory review or further disruption or delay of any pending or future litigation; delay in or failure to obtain regulatory approval of the Company's or Enalare's product candidates and successful compliance with FDA, European Medicines Agency and other governmental regulations applicable to product approvals; the outcome of litigation involving any of its products or that may have an impact on any of its products; the strength and enforceability of the Company's intellectual property rights or the rights of third parties; the risks inherent in drug development and in conducting clinical trials; the ability of Enalare to achieve milestones and deliverables under the BARDA agreement and otherwise accelerate and achieve successful results in the development of ENA-001; and those risks and uncertainties identified in the "Risk Factors" sections of the Company's Annual Report on Form 10-K for the year ended December 31, 2021, filed with the Securities and Exchange Commission (the "SEC") on March 8, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2022, filed with the SEC on May 9, 2022, the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2022, filed with the SEC on August 9, 2022 and its other subsequent filings with the SEC, which the Company expects to file with the SEC on August 9, 2022. Readers are cautioned not to place undue reliance on these forward-looking statements. All forward-looking statements contained in this press release speak only as of the date on which they were made. Except to the extent required by law, the Company undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made.

Investor Relations for Eagle Pharmaceuticals, Inc.:

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Important Safety Information **for BYFAVO™ (remimazolam) Injection**

Indications

BYFAVO is a benzodiazepine indicated for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less.

Important Safety Information

WARNING: PERSONNEL AND EQUIPMENT FOR MONITORING AND RESUSCITATION AND RISKS FROM CONCOMITANT USE WITH OPIOID ANALGESICS

Personnel and Equipment for Monitoring and Resuscitation

- **Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO.**
- **Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation.**
- **BYFAVO has been associated with hypoxia, bradycardia, and hypotension. Continuously monitor vital signs during sedation and during the recovery period.**
- **Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO.**

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of benzodiazepines, including BYFAVO, and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of intravenous BYFAVO can be accentuated by concomitantly administered CNS depressant medications, including other benzodiazepines and propofol. Continuously monitor patients for respiratory depression and depth of sedation.

Contraindication

BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Personnel and Equipment for Monitoring and Resuscitation

Clinically notable hypoxia, bradycardia, and hypotension were observed in Phase 3 studies of BYFAVO. Continuously monitor vital signs during sedation and through the recovery period. Only personnel trained in the administration of procedural sedation, and not involved in the conduct of the diagnostic or therapeutic procedure, should administer BYFAVO. Administering personnel must be trained in the detection and management of airway obstruction, hypoventilation, and apnea, including the maintenance of a patent airway, supportive ventilation, and cardiovascular resuscitation. Resuscitative drugs, and age- and size-appropriate equipment for bag-valve-mask–assisted ventilation must be immediately available during administration of BYFAVO. Consider the potential for worsened cardiorespiratory depression prior to using BYFAVO concomitantly with other drugs that have the same potential (e.g., opioid analgesics or other sedative-hypnotics). Administer supplemental oxygen to sedated patients through the recovery period. A benzodiazepine reversal agent (flumazenil) should be immediately available during administration of BYFAVO.

Risks From Concomitant Use With Opioid Analgesics and Other Sedative-Hypnotics

Concomitant use of BYFAVO and opioid analgesics may result in profound sedation, respiratory depression, coma, and death. The sedative effect of IV BYFAVO can be accentuated when administered with other CNS depressant medications (eg, other benzodiazepines and propofol). Titrate the dose of BYFAVO when administered with opioid analgesics and sedative-hypnotics to the desired clinical response. Continuously monitor sedated patients for hypotension, airway obstruction, hypoventilation, apnea, and oxygen desaturation. These cardiorespiratory effects may be more likely to occur in patients with obstructive sleep apnea, the elderly, and ASA-PS class III or IV patients.

Hypersensitivity Reactions

BYFAVO contains dextran 40, which can cause hypersensitivity reactions, including rash, urticaria, pruritus, and anaphylaxis. BYFAVO is contraindicated in patients with a history of severe hypersensitivity reaction to dextran 40 or products containing dextran 40.

Neonatal Sedation

Use of benzodiazepines during the later stages of pregnancy can result in sedation (respiratory depression, lethargy, hypotonia) in the neonate. Observe newborns for signs of sedation and manage accordingly.

Pediatric Neurotoxicity

Published animal studies demonstrate that anesthetic and sedation drugs that block NMDA receptors and/or potentiate GABA activity increase neuronal apoptosis in the developing brain and result in long-term cognitive deficits when used for longer than 3 hours. The clinical significance of this is not clear. However, the window of vulnerability to these changes is believed to correlate with exposures in the third trimester of gestation through the first several months of life but may extend out to approximately 3 years of age in humans.

Anesthetic and sedation drugs are a necessary part of the care of children needing surgery, other procedures, or tests that cannot be delayed, and no specific medications have been shown to be safer than any other. Decisions regarding the timing of any elective procedures requiring anesthesia should take into consideration the benefits of the procedure weighed against the potential risks.

Adverse Reactions

The most common adverse reactions reported in >10% of patients (N=630) receiving BYFAVO 5-30 mg (total dose) and undergoing colonoscopy (two studies) or bronchoscopy (one study) were: hypotension, hypertension, diastolic hypertension, systolic hypertension, hypoxia, and diastolic hypotension.

Use in Specific Populations

Pregnancy

There are no data on the specific effects of BYFAVO on pregnancy. Benzodiazepines cross the placenta and may produce respiratory depression and sedation in neonates. Monitor neonates exposed to benzodiazepines during pregnancy and labor for signs of sedation and respiratory depression.

Lactation

Monitor infants exposed to BYFAVO through breast milk for sedation, respiratory depression, and feeding problems. A lactating woman may consider interrupting breastfeeding and pumping and discarding breast milk during treatment and for 5 hours after BYFAVO administration.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. BYFAVO should not be used in patients less than 18 years of age.

Geriatric Use

No overall differences in safety or effectiveness were observed between these subjects and younger subjects. However, there is a potential for greater sensitivity (eg, faster onset, oversedation, confusion) in some older individuals. Administer supplemental doses of BYFAVO slowly to achieve the level of sedation required and monitor all patients closely for cardiorespiratory complications.

Hepatic Impairment

In patients with severe hepatic impairment, the dose of BYFAVO should be carefully titrated to effect. Depending on the overall status of the patient, lower frequency of supplemental doses may be needed to achieve the level of sedation required for the procedure. All patients should be monitored for sedation-related cardiorespiratory complications.

Abuse and Dependence

BYFAVO is a federally controlled substance (CIV) because it contains remimazolam which has the potential for abuse and physical dependence.